REMARKS/ARGUMENTS

Attorney Docket Number

Applicant would like to inform the Examiner that it is represented by new counsel in the present matter. As such, Applicant respectfully requests that the Attorney Docket Number for the present cased be changed from "3295-0027-C" to "OHI 1717-063." Applicant also respectfully requests that the Examiner reference this new docket number in all future correspondence relating to the present application.

Information Disclosure Statement

The Examiner's rejection of the foreign language document citations included in the June 25, 2004 Information Disclosure Statement is acknowledged.

List of Co-pending Applications

The Examiner has requested a list of all co-pending patent applications that set forth subject matter similar to the claims of the present application, and a copy of the claims thereof. To Applicant's knowledge, U.S. Application Serial No. 09/121,300, U.S. Application Serial No. 10/107,318, and U.S. Application Serial No. 10/701,426 are the only co-pending applications reciting subject matter similar to the claims of the present application. A copy of the claims of each application, in what is believed to be their current form, are attached hereto.

In the Claims:

Claims 23-25, 34-42, 44, 47-50 and 54-123 are now pending in the present application. Claims 23-25, 35-42, 44, 47-50, 65-71, 83-90 and 93-94 have been amended. Claim 43 has been canceled. New claims 97-123 have been added.

Support for the subject matter of the claims, as amended, may be found at various locations in the current application, as well as U.S. Application No. 09/131,915 (now U.S. Patent No. 6,406,499), to which the present application claims priority. Support for the shape of the covering can be found throughout the present application, as well as the specification and Figures 5-7 and 9 of U.S. Patent No. 6,406,499 (the '499 patent). With respect to the ability of the polymeric material of the present invention to provide an air-tight seal with the limb of a wearer, support may be found at least at page 2, lines 16-21 of the present application, as well as column 1, lines 57-66 of the '499 patent, wherein breathable (porous) stump socks are differentiated from polymeric socks (coverings) - such as those of the present invention. Further support for the sealing capabilities of the polymeric material (and covering) can be found at page 8, lines 13-17; page 20, lines 10-12; and page 35, lines 12-14 of the present application, as well as column 4, lines 45-51; column 8, lines 44-47; and column 13, lines 4-7 of the '499 patent.

With respect to the fiber-on-end fabric recited in several of the claims, support can be found at least at page 23, line 11 - page 24, line 21 of the present application, as well as column 10, lines 9-57 of the '499 patent. With respect to

the inclusion of a docking means on the covering, support can be found in the present application at least at page 4, line 20 - page 5, line 5; page 5, line 21 - page 6, line 2; and page 17, line 17 -page 18, line 19 of the present application, and in the '499 patent at least at column 2, line 64 to column 3, line 8; column 3, lines 31-36; and column 7, lines 41-59. With respect to the covering including a polymeric material that is coated directly to the interior of the fabric and an exemplary method of manufacture, support can be found at least at page 16, line 12; page 18, lines 1-2; page 19, lines 17-21; page 31, line 12; page 36, lines 11-14; page 37 lines 9-15; page 37, line 22 - page 38, line 5; and Examples 1-2, 4-10, and 12 of the present application, as well as column 7, lines 13-14 and lines 50-51; column 8, lines 23-28; column 11, lines 5-7; column 13, lines 35-40; column 13, line 64 - column 14, line 7; column 14, lines 17-24; and Examples 1-2, and 4-10 of the '499 patent. With respect to a covering wherein the polymeric material is thicker at the closed end than at the open end, support can be found in the present application at least at page 15, line 18 - page 16, line 7; page 37, lines 6-8 and lines 20-22, as well as in the '499 patent column 6, line 56 - column 7, line 5; column 13, lines 61-63; and column 14, lines 14-17.

Objection to Claims 23, 44 and 47-49 Under 35 U.S.C. § 112

The Examiner objected to claims 23, 44 and 47-49 under 35 U.S.C. § 112, second paragraph, as containing language that is confusing based on the location thereof in said claims. More specifically, the Examiner objects to the use of the term "comprising" in line 3 of claims 23, 44, 47 and 48, and line 4 of claim

49. Applicant has amended each of claims 23, 44 and 47-49 to more clearly describe the subject matter recited therein. Consequently, Applicant respectfully submits that the Examiners 35 U.S.C. § 112 objection to said claims is now moot and, therefore, may be properly withdrawn.

Rejection of Claims 23-25, 34-44 and 47-50 and 54-96 Under 35 U.S.C. § 112

The Examiner rejected claims 23-25, 34-44 and 47-50 and 54-96 under 35 U.S.C. § 112, second paragraph as being indefinite. More particularly, the Examiner rejected the claims for including the phrase "substantially air tight." The Examiner asserts that "substantially air tight" is a broad term for which the specification of the present application provides no measuring standard and, therefore, one of ordinary skill in the art would not be able to determine what degrees of "air tight" would and would not fall within the scope of the claims.

Although Applicant respectfully disagrees with the Examiner's assertion that the phrase "substantially air-tight" is indefinite, Applicant has nonetheless amended claims 23-25, 35-42, 44, 47-50, 67-71, 83-90 and 93-94 in an attempt to expedite allowance of the subject matter recited therein. More specifically, the phrase "substantially air-tight seal ..." has been replaced with the phrase "capable of forming an airtight seal ..." Claim 43 has been canceled. Applicant submits that the amended claim language is fully supported by the specification of the present application and by parent application 09/131,915 (now U.S. Patent No. 6,406,499) to which it claims priority. Additionally, this language better comports with the allowed claim language of U.S. Patent No. 6,406,499. As a

result of the foregoing amendments, Applicant respectfully submits that the Examiner's 35 U.S.C. § 112 objection to claims 23-25, 34-44 and 47-50 and 54-96 is now moot and, therefore, may be properly withdrawn.

Rejection of Claims 24-25, 34-37, 42, 44, 48, 54, 58, 60, 62, 67, 72, 76, 78, 80 and 96 Under 35 U.S.C. § 102(b)

The Examiner rejected claims 24-25, 34-37, 42, 44, 48, 54, 58, 60, 62, 67, 72, 76, 78, 80 and 96 under 35 U.S.C. § 102(b) as being anticipated by Lerman (US 4,635,626). Applicant has amended claims 23-25, 35-42, 44, 47-50, 67-71, 83-90 and 93-94 to more clearly describe the subject matter recited therein. As Applicant does not believe Lerman to teach the subject matter of said claims, the rejection is respectfully traversed.

Lerman teaches two variations of a prosthetic stocking (stump sock): a temporary post-operative stump sock, and a permanent stump sock. The temporary stump sock is shown in Fig. 1, and is said to be made from a composite material **10** including a base layer **32** of a flexible and resilient *open-cell* foam material. It is specifically stated that the open-cell material used for the base layer was selected because it *breathes* - meaning it is *porous to air and water* - and, therefore, ensures good air circulation to the stump. (See column 3, lines 62-65). To an inside face of the base layer is adhered an inner layer **34** of a material that is also porous to air and water. (See column 3, line 67 - column 4, line 2). A preferred inner layer material is velour. An outer layer **38** of a flexible and stretchable cloth is adhered to an outer face of the base layer. This outer layer is also said to be porous to air and water. (See column 3, lines 9-12). The

inner layer **34** and the outer layer **38** are adhered to the base layer **32** by separate adhesive layers **36**, **40**, respectively. A conventional spray-on adhesive is said to provide the desired adhesion between layers. As a result of such material selection and construction, the composite material of Lerman is porous to both air and water (and other gases and fluids) and, consequently, a temporary stump sock made therefrom is *incapable of forming an air-tight seal* with the limb of a wearer.

Similarly, the permanent stump sock (see Figs. 6-7) is made from a composite material **50** including a base layer **52** of a flexible and resilient *open-cell* material - such as sponge rubber. Like the material selected for use in the base layer **32** of the temporary stump sock, the material of the permanent stump sock base layer **52** is also porous to air and water. (See column 5, lines 23-24). An outer layer **56** of a material similar or identical to that used with the temporary stump sock is also provided on the permanent stump sock. The permanent stump sock is also provided with an inner layer **54** of the same or a similar material (as opposed to the velour material used for the inner layer of the temporary stump sock). Both the inner layer **54** and outer layer **56** of the temporary stump sock are comprised of materials that are porous to air and water. (See column 5, lines 33-34). Therefore, as with the temporary stump sock discussed supra, the composite material used to make a permanent stump sock is porous to both air and water (and other gases and fluids) and, consequently, the permanent stump sock of Lerman is also *incapable of forming an air-tight seal* with the limb of a wearer.

From the foregoing analysis, it can be understood that while the temporary stump sock and permanent stump sock may have slightly different constructions, it is clear that the main objective of both designs is to allow air and/or other fluids to easily pass therethrough. It is particularly stated that the breathability of the temporary stump sock base material not only ensures good air circulation to the stump, but also facilitates the dissipation of heat and the absorption of fluids during the healing process. (See column 3, lines 62-66). It can be logically inferred that the specified porous materials are used in the construction of the permanent stump sock to achieve the same objective.

In contrast, the claims of the present application are directed to a tube-shaped covering for an amputation stump, wherein the covering is comprised of a fabric and at least one polymeric material that is capable of forming an air-tight seal with a limb of a wearer when donned. It is the polymeric material of the present invention that contacts the wearer's skin, therefore it is the polymeric material that is also responsible for producing the air-tight seal. Consequently, the polymeric material, *as recited in the present claims*, is not, and cannot be, porous to air and water - as is the composite material described in Lerman. If the polymeric material of the present invention were able to "breathe," as does the material in Lerman, an air-tight seal could never be formed thereby.

The advantages of forming a covering as claimed in the present application can be inherently understood, and have also been specifically discussed in the specification thereof, as well as in previous responses to the Examiner's claim rejections. Such advantages may include, without limitation:

the ability to use the covering as a suspension device, wherein docking means can be optionally included on the covering and used to couple the covering (and stump) to a prosthetic limb; the ability to impregnate the polymeric material with one or more additives that can be released therefrom on a timed-release basis; the ability to maintain a positive air pressure within the covering; prevention of perspiration transfer from the interior of the covering to its outside surface; and the ability to wear the covering during activities such as bathing or swimming without having to subsequently change the covering before donning a prosthetic limb.

A stump sock as taught by Lerman cannot provide these advantages, and many others, because of the porous nature of the material from which it is constructed. More specifically, as the stump socks of Lerman are intentionally designed to be porous to both air and water, they cannot form an air-tight seal with a wearer's limb or prevent the transfer of fluids therethrough. Thus, the stump socks of Lerman cannot be used to, for example, retain a prosthetic limb on the residual limb of an amputee, cannot be used to provide the timed-release of additives to the residual limb, cannot prevent the transfer of perspiration from the residual limb to the outside surface of the sock (covering); and cannot be worn during bathing, swimming, or similar activities without being changed before the subsequent donning of a prosthetic limb. More simplistically stated, the stump socks of Lerman are considerably different from the amputation stump covering claimed in the present application - both in construction and performance.

It is noted by Applicant that Lerman does mention the possible use of neoprene rubber as the base layer of the composite used to make the permanent stump sock. However, it is expressly stated that such a material is disfavored due to its closed-cell composition. (See column 5, lines 21-23). In addition, even if a closed-cell neoprene rubber were used as the base layer in Lerman, it is still required that its inner surface have a fabric layer adhered thereto. (See column 5, lines 27-29; and Fig. 7). As such, even this theoretical, but disfavored embodiment of the Lerman stump sock, fails to teach the amputation stump covering as claimed in the present application.

Based on the foregoing analysis, it can be understood that significant differences exist between the teachings of Lerman and the subject matter of the rejected claims. As such, Applicant respectfully submits that Lerman cannot support a rejection of claims 24-25, 34-37, 42, 44, 48, 54, 58, 60, 62, 67, 72, 76, 78, 80 and 96 under 35 U.S.C. § 102(b).

Rejection of Claims 23-25, 34-35, 37-38, 41-44, 47-50, 54-62, 65-68, 71-80, 83-86, 89-90 and 93-96 Under 35 U.S.C. § 102(b)

The Examiner rejected claims 23-25, 34-35, 37-38, 41-44, 47-50, 54-62, 65-68, 71-80, 83-86, 89-90 and 93-96 under 35 U.S.C. § 102(b) as being anticipated by Kania (US 5,603,122). Applicant has amended claims 23-25, 35-42, 44, 47-50, 67-71, 83-90 and 93-94, and has canceled claim 43. As a result of these amendments, Applicant submits that the subject matter of the rejected claims is fully supported by the present application, as well as by the

specification of U.S. Application 09/131,915 (now U.S. Patent No. 6,406,499), to which the present application claims priority. U.S. Application 09/131,915 was a continuation of U.S. Application 08/688,954, filed on July 31, 1996, now abandoned. Since the rejected claims are fully supported in the present application by subject matter also present in U.S. Application 09/131,915, which claims priority to the July 31, 1996 filing date of U.S. Application 08/688,954, Applicant respectfully submits that the rejected claims are also entitled to an effective filing date of July 31, 1996 - not the later October 15, 1999 date, as suggested by the Examiner. Both the Kania '122 patent and the present application have a single and identical inventor. The Kania '122 patent also did not issue until February 18, 1997. Consequently, as Applicant believes the subject matter of the rejected claims to have an effective filing date of July 31, 1996, Applicant respectfully submits that Kania '122 cannot be used to support the rejection of said claims.

Rejection of Claims 39-40, 69-70, and 87-88 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 39-40, 69-70, and 87-88 under 35 U.S.C. § 103(a) as being unpatentable over Kania (US 5,603,122) in view of Handal (US 5,263,990). As discussed above, Applicant does not believe Kania to qualify as prior art against the rejected claims. Applicant also does not believe Handal to teach or suggest the subject matter of claims 39-40, 69-70, and 87-88. As such, the rejection is respectfully traversed.

Handal, with or without Kania, simply does not teach or suggest the subject matter of the rejected claims. Rather, Handal teaches a prosthetic limb socket that is designed to be integral with a wrist unit. The object of Handal is to provide a socket that can stand up to heavy use without breaking or deforming. Thus, the prosthetic socket is comprised of a rigid material, such as a resin reinforced with fiberglass or synthetic fibers. A foam fitting member can be placed inside the socket to provide a better fit between an amputee's residual limb and the socket. The foam fitting member can be replaced as changes in residual limb size and/or shape occur.

Thus, Handal does not teach or suggest a tube-shaped covering for enclosing an amputation stump, wherein a fabric is coated on the interior thereof with a polymeric material capable of forming an air-tight seal with the limb of a wearer when the covering is donned. There is no use of a fabric mentioned in Handal nor, obviously, of coating the interior of such a fabric with a polymeric material. Additionally, the polymeric material recited in the presently rejected claims is dissimilar to the foamed (i.e., open-cell) materials suggested for use in the fitting member of Handal. Further, Handal does not appear to teach or suggest that the foam fitting member or any other part of the socket can provide an air-tight seal with a wearer's limb.

With respect to the Examiner's assertion that Handal teaches the uneven distribution of polymeric material as recited in claims 40, 70 and 88, Applicant respectfully disagrees. Each of claims 40, 70, and 88, now recites that "said covering has an uneven distribution of polymeric material that results in a thinner

posterior middle and upper portion, and a thicker distal anterior medial and anterior lateral portion." In other words, the covering recited in claims 40, 70 and 88 includes a thinned middle and upper portion along its rear, and a thickened portion at its distal end that coincides with the inner and outer sides of the residual limb. No such distribution of any material is taught or suggested by Handal. Rather, as can be seen in Fig. 2 of Handal, the foam fitting member tapers substantially uniformly from a thicker section near its closed end to a thinner section near its open end.

Therefore, Applicant asserts that Kania does not qualify as prior art against the rejected claims, and Handal does not teach or suggest the subject matter of the rejected claims. As such, Applicant respectfully submits that Kania in view of Handal cannot support a rejection of claims 39-40, 69-70, and 87-88 under 35 U.S.C. § 103(a).

Rejection of Claims 63-64, 81-82, and 91-92 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 63-64, 81-82, and 91-92 under 35 U.S.C. § 103(a) as being unpatentable over Kania (US 5,603,122) alone. Applicant has discussed, above, why Kania does not qualify as prior art against the claims of the present application, as amended. As such, Applicant respectfully submits that Kania cannot be used to support a rejection of claims 39-40, 69-70, and 87-88 under 35 U.S.C. § 103(a).

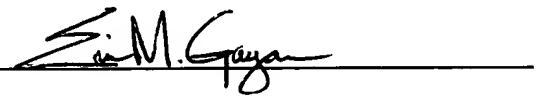
CONCLUSION

Applicant has amended claims 23-25, 35-42, 44, 47-50, 65-71, 83-90 and 93-94, has canceled claim 43, and has added new claims 97-123. No new material has been added. Applicant has also distinguished the subject matter of the present invention over the teachings of the references cited as prior art by the Examiner.

Therefore, Applicant respectfully submits that the present application is now in condition for allowance, and entry of the present amendment and allowance of the application as amended is earnestly requested. Telephone inquiry to the undersigned in order to clarify or otherwise expedite prosecution of the present application is respectfully encouraged.

Respectfully submitted,

Date: 11-18-04

By: 

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CLAIMS OF APPLICATION SERIAL NO. 09/121,300

Listing of Claims:

Claims 1-74 (canceled).

Claim 75 (previously presented): A cushion liner for enclosing an amputation stump, said liner comprising a fabric stump covering having an open end for introduction of said stump and a closed end opposite said open end, said fabric coated seamlessly on only the inside thereof with a nonporous polymeric cushioning material, wherein said polymeric cushioning material optionally has a thickness profile such that the polymeric cushioning material is thicker at a closed end of the covering than at an open end; wherein said nonporous polymeric cushioning material is configured to contact the skin of the amputation stump when worn by a user, and is substantially nonporous to air and water.

Claim 76 (previously presented): The cushion liner as claimed in claim 75, wherein said fabric is coated on the inside thereof with an uneven distribution of said nonporous polymeric cushioning material, said uneven distribution comprising a thinner posterior middle and upper, and a thicker distal anterior-medial and anterior-lateral.

Claim 77 (previously presented): The cushion liner as claimed in claim 75, wherein said nonporous polymeric cushioning material is arranged in a recess Achilles configuration.

Claim 78 (previously presented): The cushion liner as claimed in claim 75, having a length from closed end to open end of from 10-25 inches.

Claim 79 (canceled).

Claim 80 (previously presented): The cushion liner as claimed in claim 75, wherein said nonporous polymeric cushioning material has a thickness varying from 0.150-0.500 inches.

Claims 81-84 (canceled).

Claim 85 (previously presented): The cushion liner as claimed in claim 75, completely coated on only the inside thereof with nonporous polymeric cushioning material.

Claim 86 (previously presented): The cushion liner as claimed in claim 83, completely coated on only the inside thereof with said nonporous polymeric cushioning material.

Claim 87 (canceled).

Claim 88 (previously presented): The cushion liner as claimed in claim 75, wherein said nonporous polymeric cushioning material comprises a biocide.

Claim 89 (previously presented): The cushion liner as claimed in claim 75, wherein said nonporous polymeric cushioning material comprises a vitamin.

Claims 90-91 (canceled).

Claim 92 (previously presented): A cushion liner for enclosing an amputation stump, said liner comprising a fabric stump covering having an open end for introduction of said stump and a closed end opposite said open end, said fabric coated seamlessly on only the inside thereof with a nonporous polymeric cushioning material, wherein said polymeric cushioning material has a thickness

profile such that the polymeric cushioning material is thicker at a closed end of the covering than at an open end; wherein said nonporous polymeric cushioning material is configured to contact the skin of the amputation stump when worn by a user, and is substantially nonporous to air and water.

Claim 93 (previously presented): The cushion liner as claimed in claim 92, wherein said fabric is coated on the inside thereof with an uneven distribution of said nonporous polymeric cushioning material, said uneven distribution comprising a thinner posterior middle and upper, and a thicker distal anterior-medial and anterior-lateral.

Claim 94 (previously presented): The cushion liner as claimed in claim 92, wherein said nonporous polymeric cushioning material is arranged in a recess Achilles configuration.

Claim 95 (canceled).

Claim 96 (previously presented): The cushion liner as claimed in claim 92, wherein said nonporous polymeric cushioning material has a thickness varying from 0.150-0.500 inches.

Claims 97-98 (canceled).

Claim 99 (previously presented): The cushion liner as claimed in claim 92, completely coated on only the inside thereof with said nonporous polymeric cushioning material.

Claims 100-101 (canceled).

Claim 102 (previously presented): The cushion liner as claimed in claim 92, wherein said nonporous polymeric cushioning material comprises a biocide.

Claim 103 (previously presented): The cushion liner as claimed in claim 92, wherein said nonporous polymeric cushioning material comprises a vitamin.

Claims 104-105 (canceled).

Claim 106 (previously presented): A cushion liner for enclosing an amputation stump, said liner comprising a fabric stump covering having an open end for introduction of said stump and a closed end opposite said open end, said fabric coated seamlessly and directly on only the inside thereof with said-a nonporous polymeric cushioning material, wherein said nonporous polymeric cushioning material optionally has a thickness profile such that said nonporous polymeric cushioning material is thicker at a closed end of the covering than at an open end; and wherein said nonporous polymeric cushioning material is configured to contact the skin of the amputation stump when worn by a user, and is substantially nonporous to air and water.

Claim 107 (previously presented): The cushion liner as claimed in claim 106, wherein said nonporous polymeric cushioning material has a thickness varying from 0.150-0.500 inches.

Claims 108-109 (canceled).

Claim 110 (previously presented): A cushion liner for enclosing an amputation stump, said liner comprising a fabric stump covering having an open end for introduction of said stump and a closed end opposite said open end, said fabric

coated seamlessly and directly on only the inside thereof with said-a nonporous polymeric cushioning material, wherein said nonporous polymeric cushioning material has a thickness profile such that the said nonporous polymeric cushioning material is thicker at a closed end of the covering than at an open end; and wherein said nonporous polymeric cushioning material is configured to contact the skin of the amputation stump when worn by a user, and is substantially nonporous to air and water.

Claim 111 (previously presented): The cushion liner as claimed in claim 110, wherein said nonporous polymeric cushioning material has a thickness varying from 0.150 - 0.500 inches.

Claims 112-113 (canceled).

Claim 114 (previously presented): A cushion liner for enclosing an amputation stump, said liner comprising a fabric stump covering having an open end for introduction of said stump and a closed end opposite said open end, said fabric coated on only the inside thereof with said-a nonporous polymeric cushioning material, wherein said nonporous polymeric cushioning material optionally has a thickness profile such that said nonporous polymeric cushioning material is thicker at the closed end of the covering than at an open end, wherein said liner can be donned by inverting and rolling onto the amputation stump; and wherein said nonporous polymeric cushioning material is configured to contact the skin of the amputation stump when worn by a user, and is substantially nonporous to air and water.

Claim 115 (previously presented): The cushion liner as claimed in claim 114, wherein said nonporous polymeric cushioning material has a thickness varying from 0.150 - 0.500 inches.

Claims 116-117 (canceled).

Claim 118 (previously presented): A cushion liner for enclosing an amputation stump, said liner comprising a fabric stump covering having an open end for introduction of said stump and a closed end opposite said open end, said fabric coated on only the inside thereof with said-a nonporous polymeric cushioning material, wherein said nonporous polymeric cushioning material has a thickness profile such that said nonporous polymeric cushioning material is thicker at the closed end of the covering than at an open end, wherein said liner can be donned by inverting and rolling onto the amputation stump; and wherein said nonporous polymeric cushioning material is configured to contact the skin of the amputation stump when worn by a user, and is substantially nonporous to air and water.

Claim 119 (previously presented): The cushion liner as claimed in claim 118, wherein said nonporous polymeric cushioning material has a thickness varying from 0.150 - 0.500 inches.

Claim 120 (previously presented): The cushion liner as claimed in claim 118, further comprising docking means at the distal end thereof.

Claim 121 (previously presented): The cushion liner as claimed in claim 120, wherein said docking means is molded to said fabric on an exterior of said liner.

Claim 122 (previously presented): A cushion liner for enclosing an amputation stump, said liner having an open end for introduction of said stump and a closed end opposite said open end, said liner comprising a nonporous polymeric cushioning material, wherein said polymeric cushioning material optionally has a thickness profile such that the polymeric cushioning material is thicker at a closed end of the covering than at an open end; wherein said nonporous polymeric cushioning material is configured to contact the skin of the amputation stump when worn by a user, and is substantially nonporous to air and water.

Claim 123 (previously presented): The cushion liner as claimed in claim 122, wherein said nonporous polymeric cushioning material has a thickness varying from 0.150-0.500 inches.

CLAIMS OF APPLICATION SERIAL NO. 10/107,318

(Prior to Non-entered Amendment of 08/10/2004)

Listing of Claims:

Claims 1-14 (canceled).

Claim 15 (previously presented): An open-ended cushion sleeve for use by an amputee or non-amputee, said open-ended sleeve being curved-shaped and having an inside and an outside, said sleeve comprising a foamed or non-foamed gel composition having a Shore 00 durometer of from 1-100 and comprising a styrene-ethylene/propylene, styrene -ethylene/butylene-styrene or styrene isoprene/butadiene block copolymer and, optionally, up to 90% by weight, of mineral oil based on total weight of copolymer and oil; wherein the gel composition has a thickness of a distal portion that is greater than a thickness of at least one of a proximal portion and a middle portion.

Claim 16 (previously presented): The sleeve as claimed in Claim 15, further comprising a reinforcing material having an elasticity lower than said gel and arranged in said sleeve so as to protect said amputee or non-amputee and/or said sleeve from stress and/or abrasion when worn.

Claim 17 (previously presented): The sleeve as claimed in 15, wherein said sleeve further comprises fabric which coats part or all of said gel on at least one side thereof.

Claim 18 (previously presented): The sleeve as claimed in 15, having said gel or a thermoplastic elastomer or a thermoset elastomer arranged so as to be capable of forming an air-tight seal with a limb or prosthetic hard socket when

worn.

Claim 19 (previously presented): The sleeve as claimed in Claim 15, wherein the elasticity of said sleeve is higher circumferentially than axially.

Claims 20 - 21 (cancelled).

Claim 22 (previously presented): The sleeve as claimed in Claim 15, wherein a length of the sleeve is selected from a range of about 1-25 inches.

Claim 23 (previously presented): The sleeve as claimed in Claim 15, wherein said gel composition comprises a coupling with a seam; wherein a first side and a second side of the fabric such that a continuous curve shape is formed.

Claim 24 - 26 (cancelled).

Claim 27 (previously presented): The sleeve as claimed in Claim 15, which further comprises an air-tight-forming band configured to form a suction suspension system and disposed on one of the inside and the outside.

Claims 28-29 (cancelled).

Claim 30 (previously presented): The sleeve as claimed in Claim 15, wherein the sleeve is cylinder-shaped.

Claim 31 (previously presented): The sleeve as claimed in Claim 15, wherein the sleeve is substantially conical-shaped.

Claim 32 (previously presented): The sleeve as claimed in Claim 17, wherein the fabric comprises fibers which are at least one of a non-uniform type and a

uniform type.

Claim 33 (previously presented): The sleeve as claimed in Claim 17, wherein the fabric is disposed on a middle section of the inside of the open-ended sleeve.

Claim 34 (previously presented): The sleeve as claimed in Claim 17, wherein the fabric comprises elastic material which is stretchable in at least one direction.

Claim 35 (previously presented): The sleeve as claimed in Claim 17, wherein the fabric comprises a material which is at least one material selected from the group consisting of nylon, neoprene, stretchable non-woven, elastomeric polyurethane fibers, elastic supplex nylon, spunbonded olefin, spunlaced fabric, polyester aramid fiber fabrics and looped nylon.

Claim 36 (previously presented): The sleeve as claimed in Claim 17, wherein the fabric is of a thickness in a range from about 0.010 inches to 0.200 inches.

Claim 37 (previously presented): The sleeve as claimed in Claim 17, further comprises a reinforcing material disposed on at least one of the inside and the outside.

Claim 38 (previously presented): The sleeve as claimed in Claim 18, wherein the gel composition or the thermoplastic elastomer or the thermoset elastomer forms a surface configured to contact the limb or the prosthetic hard socket and which is substantially smooth.

Claim 39 (previously presented): The sleeve as claimed in Claim 38, wherein the surface comprises a material which is at least one material selected from

the group consisting of a dip coat application material, a melt coat application material and a solvent evaporation coated material.

Claim 40 (previously presented): An open-ended cushion sleeve for use by an amputee or non-amputee, said open-ended sleeve being curved-shaped and having an inside and an outside, said sleeve comprising a foamed or non-foamed gel composition having a Shore 00 durometer of from 1-100 and comprising a styrene-ethylene/propylene, styrene-ethylene/butylene-styrene or styrene isoprene/butadiene block copolymer and, optionally, up to 90% by weight, of mineral oil based on total weight of copolymer and oil; wherein the gel composition has a thickness of a distal portion that is greater than a thickness of at least one of a proximal portion and a middle portion.

Claim 41 (previously presented): The sleeve as claimed in Claim 40, further comprising a reinforcing material having an elasticity lower than said gel and arranged in said sleeve so as to protect said amputee or non-amputee and/or said sleeve from stress and/or abrasion when worn.

Claim 42 (previously presented): The sleeve as claimed in Claim 40, wherein said sleeve further comprises fabric which coats part or all of said gel on at least one side thereof.

Claim 43 (previously presented): The sleeve as claimed in Claim 40, having said gel or a thermoplastic elastomer or a thermoset elastomer arranged so as to be capable of forming an air-tight seal with a limb or prosthetic hard socket when worn.

Claim 44 (previously presented): The sleeve as claimed in Claim 40, wherein the elasticity of said sleeve is higher circumferentially than axially.

Claim 45 (previously presented): The sleeve as claimed in Claim 40,wherein a length of the sleeve is selected from a range of about 1-25 inches.

Claim 46 (previously presented): The sleeve as claimed in Claim 40, wherein said gel composition comprises a coupling with a seam; wherein a first side and a second side of the fabric such that a continuous curved shape is formed.

Claim 47 (previously presented): The sleeve as claimed in Claim 40, which further comprises an air-tight-forming band configured to form a suction suspension system and disposed on one of the inside and the outside.

Claim 48 (previously presented): The sleeve as claimed in Claim 40, wherein the sleeve is cylinder-shaped.

Claim 49 (previously presented): The sleeve as claimed in Claim 40, wherein the sleeve is substantially conical-shaped.

Claim 50 (previously presented): The sleeve as claimed in Claim 42, wherein the fabric comprises fibers which are at least one of a non-uniform type and a uniform type.

Claim 51 (previously presented): The sleeve as claimed in Claim 42, wherein the fabric is disposed on a middle section of the inside of the open-ended sleeve.

Claim 52 (previously presented): The sleeve as claimed in Claim 42, wherein the fabric comprises elastic material which is stretchable in at least one direction.

Claim 53 (previously presented): The sleeve as claimed in Claim 42, wherein the fabric comprises a material which is at least one material selected from the group consisting of nylon, neoprene, stretchable non-wovens, elastomeric polyurethane fibers, elastic supplex nylon, spunbonded olefin, spunlaced fabric, polyester aramid fiber fabrics and looped nylon.

Claim 54 (previously presented): The sleeve as claimed in Claim 42, wherein the fabric is of a thickness in a range from about 0.010 inches to 0.200 inches.

Claim 55 (previously presented): The sleeve as claimed in Claim 42, further comprising a reinforcing material disposed on at least one of the inside and the outside.

Claim 56 (previously presented): The sleeve as claimed in Claim 43, wherein the gel composition or the thermoplastic elastomer or the thermoset elastomer forms a surface configured to contact the limb or the prosthetic hard socket and which is substantially smooth.

Claim 57 (previously presented): The sleeve as claimed in Claim 56, wherein the surface comprises a material which is at least one material selected from the group consisting of a dip coat application material, a melt coat application material and a solvent evaporation coated material.

CLAIMS OF APPLICATION SERIAL NO. 10/701,426

Listing of Claims:

Claim 1 (original): An open-ended sleeve for use by an amputee or non-amputee, said open-ended sleeve being made of a stretchable fabric and adapted to extend from a position above a knee of a wearer to a position below the knee of a wearer, said fabric being predominantly stretchable in a circumferential direction above, below, and behind the knee of a wearer and predominantly stretchable in a longitudinal direction in the area of the knee of a wearer.

Claim 2 (original): An open-ended sleeve for use by an amputee or non-amputee, said open-ended sleeve being made of elastic fabric, said sleeve being adapted to extend above and below a knee of a wearer, said sleeve comprising a front portion adapted to cover the knee of a wearer and a back portion, the front portion comprising a thicker, higher wear resistant elastic fabric and the back portion comprising a thinner, highly elastic fabric.

Claim 3 (original): An open-ended sleeve according to claim 2, wherein the front portion of the sleeve is substantially centered with respect to the knee of a wearer and extends circumferentially around the sleeve for a distance of from about 10% to about 90% of the total circumference of the sleeve.

Claim 4 (original): An open-ended sleeve for use by an amputee or non-amputee, said open-ended sleeve being made of fabric coated on one side thereof with polymeric material , wherein said polymeric material comprises at least one styrene-isobutylene-styrene block copolymer or star-branched, tapered block copolymer.

Claim 5 (original): An open-ended sleeve according to claim 4, wherein said polymeric material also comprises mineral oil.

Claim 6 (original): An open-ended elastomeric sleeve for use by an amputee or non-amputee, said open-ended sleeve comprising a first open end, a second open end, and an intermediate portion provided between said first open end and said second open end, said sleeve further comprising fabric which coats the outside of the first open end, the second open end, and the intermediate portion, and the inside of the intermediate portion only, and said intermediate portion has some means for attaching to a prosthetic socket.

Claim 7 (original): The sleeve as claimed in claim 6, wherein some or all of said fabric is fiber-on-end fabric.

Claim 8 (original): A tube sock-shaped covering for enclosing an amputation stump, said covering having an open end for introduction of said stump and a closed end opposite said open end, said covering comprising one or more high-stretch portions, and one or more no-stretch or low-stretch portions, said covering being coated on the inside thereof with a foamed or a non-foamed polymeric material.

Claim 9 (original): A tube sock-shaped covering for enclosing an amputation stump, said covering having an open end for introduction of said stump and a closed end opposite said open end, said covering comprising two or more portions connected with a type 607 stitch, said covering being coated on the inside thereof with a foamed or a non-foamed polymeric material.

Claim 10 (original): The covering of claim 9, wherein said type 607 stitch is a butt seam, lap seam, or tape seam.

Claim 11 (original): A tube sock-shaped covering for enclosing an amputation stump, said covering having an open end for introduction of said stump and a closed end opposite said open end, said covering having a docking means for suspension of the covering to the wearer, and said covering being coated on the inside thereof with polymeric material, wherein said polymeric material comprises at least one styrene-isobutylene-styrene block copolymer.

Claim 12 (original): Claim 11 - docking means limitation.

Claim 13 (original): Claim 12, but wherein the polymeric material comprises at least one of Kraton RP6917, RP6924, RP6933, RP6935, RP6936, and MD6933 and Septon 4044 and 4077.

Claim 14 (original): Claim 12, but wherein the polymeric material comprises at least one star-branched, tapered block copolymer.

Claim 15 (original): Claim 12, but wherein the polymeric material comprises at least one silicone-based thermoplastic vulcanizate.

Claim 16 (original): A gel composition comprising at least one styrene-isobutylene-styrene block copolymer and mineral oil.

Claim 17 (original): The gel composition of claim 16 bonded to fabric.

Claim 18 (original): A gel composition comprising at least one block copolymer, mineral oil, and at least one of the following antimicrobial agents:

Quaternary Ammonium Compound, Triclosan, and silver ions.

Claim 19 (original): The gel composition of claim 18, wherein said Quaternary Ammonium Compound is Benzalkonium Chloride.

Claim 20 (original): The gel composition of claim 18 bonded to fabric.